

### **REMARKS**

Upon entry of the present amendments, claims 1-10, 12-17, 21, 23-29, and 44-45 will be pending in the application. Claims 7, 21, 23, 28, and 44 have been amended herein to more precisely define the claimed invention. No new matter has been added.

#### **Formal Matters**

Applicants note with appreciation that the rejection of claims 7 and 13 under 35 U.S.C. § 112, first paragraph has been withdrawn.

Applicants note with appreciation that the rejection of claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite, has been withdrawn.

Applicants note with appreciation that the rejection of claims 7 and 8 under 35 U.S.C. § 112, second paragraph has been withdrawn.

Applicants note with appreciation that the rejection of claims 1-13 under 35 U.S.C. § 112, second paragraph, as being incomplete, has been withdrawn.

Applicants note with appreciation that the rejection of claims 21-22 under 35 U.S.C. § 112, second paragraph, as being indefinite, has been withdrawn.

#### **Allowed Claims**

Applicants note with appreciation that claims 14, 17, and 29 are allowed.

#### **Claim Rejections -- 35 U.S.C. § 112, first paragraph**

Claims 21, 23, and 28 (and dependent claims 24-27) have been rejected under 35 U.S.C. § 112, first paragraph for reciting “progenitors” which do not “initiate neurospheres”. (*See* Office Action at page 3). In response, Applicants have amended claims 21, 23, and 28 to clarify that the claimed methods involve the enrichment of neural stem cells (CNS-SC), which can

initiate neurospheres (NS-IC); progenitors; or a combination thereof. Thus, Applicants contend that this rejection has been overcome and should be withdrawn.

Claim 44 has been rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which is not enabling. According to the Examiner, “[t]he appropriate ATCC numbers and required Deposit information critical or essential to the practice of the invention, as it relates to monoclonal antibodies [*sic*] SC111, but not included in the claim(s) is not enabled by the disclosure . . .” (Office Action at page 3).

In response, Applicants have amended claim 44 to delete the reference to monoclonal antibody SC111. As such, Applicants contend that this rejection has been overcome and should be withdrawn.

Claims 1-9, 12, 15-16, 21, 23-27, 28 & 44-45 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, “the specification, while being enabling for a method for producing a population of enriched human CNS stem cells using identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating enriched populations of human CNS stem cells using unknown or uncharacterized ‘reagent[s] that specifically binds to the CD49f antigen’, and/or that no longer bind to a CD24 antigen.” (Office Action at pages 3-4). The Examiner further states that “an invitation for others to make the required monoclonal antibodies to practice the claimed methods does not reasonably enable the current invention without further defined structural characteristics . . .” (Office Action at page 4). Applicants traverse.

As an initial matter, Applicants note that claims 21 and 23 specify that the reagent that binds to CD49f is selected from the group consisting of monoclonal antibody GoH3 and monoclonal antibody 4F10. There is no reference in these claims to CD24 or to CD133. Thus, this rejection, as it applies to these claims, is moot and should be withdrawn. Similarly, claims 24-27 each depend from claim 23. As such, they necessarily contain all of the limitations of that claim. Therefore, for the reasons articulated above, Applicants contend that this rejection, as it applies to claims 24-27, is also moot and should be withdrawn.

Likewise, claim 28 also specifies (in part) that the anti-CD49f monoclonal antibody is monoclonal antibody GoH3 or monoclonal antibody 4F10. Thus, Applicants submit that this rejection, as it applies to claim 28 (in part), has also been overcome and should be withdrawn.

With respect to the rejection of claims 1-9, 12, 15-16, 28 (in part), and 44-45, Applicants note that the instant specification provides ample guidance to enable those skilled in the art to make and use the invention recited in these claims without undue experimentation. Contrary to the Examiner's contention, these claims do not contain "an invitation for others to make the required monoclonal antibodies to practice the claimed methods . . ." (Office Action at page 4). "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." (MPEP § 2164.01. *See also In re Angstadt*, 537 F.2d 498, 504).

CD49f, CD133, and CD24 are all well-known antigens. Thus, Applicant submits that it would not require undue experimentation on the part of the ordinarily skilled artisan to generate monoclonal antibodies that bind to such well-known antigens. Moreover, the instant specification provides examples of commercially available antibodies that recognize these well known antigens. (*See, e.g.*, specification at page 16, line 30 through page 17, line 7 for antibodies that recognize CD49f; page 14, line 30 through page 15, line 4 for antibodies that bind to CD133; and page 15, line 22 through page 16, line 9 for antibodies that bind to CD24).

Specifically, claim 1 (and dependent claims 2-6) recites the use of a monoclonal antibody that binds to CD49f. Claim 7, which depends from claim 1, further recites the use of a monoclonal antibody that binds to the CD24 antigen, while dependent claims 8 and 9 (which also depend from claim 1) further recite the use of a monoclonal antibody that binds to CD133. Moreover, as amended herein, claim 44 depends from claim 8 or claim 9 and specifies that the monoclonal antibody that binds to CD133 is monoclonal antibody AC133. Similarly, claim 45 which depends from claim 7, specifies that the monoclonal antibody that binds to the CD24 antigen is monoclonal antibody SC20. Thus, Applicant submits that those skilled in the art will be able to identify, make, and/or use the monoclonal antibodies described in these claims without undue experimentation.

In addition, because CD24 and CD49f are well-known antigens, Applicant contends that those skilled in the art would also be able to identify and/or isolate cells that are CD24<sup>-lo</sup> (*see*

claims 12, 15, 16, and 28), that are CD24<sup>+</sup> (*see* claims 15 and 16), and that are CD49f<sup>+</sup> (*see* claims 16 and 28) without undue experimentation.

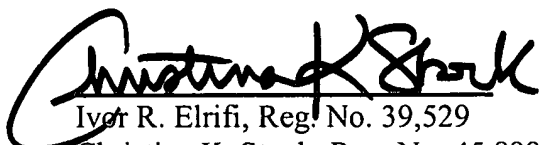
Therefore, based on the level of skill in the art as well as the teachings of the instant specification, Applicants submit that those skilled in the art would be able to practice the methods disclosed in claims 1-9, 12, 15-16, 28, and 44-45 without undue experimentation. Thus, contrary to the Examiner's contention, these claims are fully enabled by the as-filed specification. As such, this rejection should be withdrawn.

### CONCLUSION

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Christina K. Stock", is written over a horizontal line.

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